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Multichannel Negative Pressure Wound Therapy Vacuum Assisted Closure (V.A.C.™)

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Kinetic Concepts, Inc., San Antonio, TX

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Final Report
for May 2013 to February 2016

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The objective of this project was to design and develop a prototype multichannel negative pressure wound therapy (NPWT) device that permits management of up to four wounds on a patient. The goal was to reduce the overall physical footprint and weight of therapy devices used to protect wounds and remove exudate from multiple wounds on a single critically injured patient. The NPWT device was designed to be compatible with existing Kinetic Concepts, Inc. disposable wound dressings and wound exudate canisters. It was also designed to have four independently controlled NPWT channels.

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1.0 SUMMARY

The objective of this project was to design and develop a prototype multichannel negative pressure wound therapy (NPWT) device that permits management of up to four wounds on a patient. The goal was to reduce the overall physical footprint and weight of therapy devices used to protect wounds and remove exudate from multiple wounds on a single critically injured patient. The NPWT device was designed to be compatible with existing Kinetic Concepts, Inc. disposable wound dressings and wound exudate canisters. It was also designed to have four independently controlled NPWT channels.

2.0 INTRODUCTION

The United States Air Force (USAF) awarded Kinetic Concepts, Inc. (KCI) a Technology Investment Agreement to enhance the ability to rapidly but safely transport patients from point of injury to definitive care while reducing equipment footprint and variability and improving efficiency. The scope of this en route care and expeditionary medicine project includes investigating the (1) reduction of the overall physical footprint and weight of therapy devices used to protect wounds and remove exudate from multiple wounds on a single critically injured patient and (2) development of multichannel therapy capability that permits management of up to four wounds on a patient during en route care.

3.0 CONCEPT PHASE

The first phase of the project was concept. The phase began with a kickoff and user needs meeting conducted on site at KCI facilities in San Antonio, Texas, with both KCI and USAF staff present. The USAF provided an initial list of product requirements generated from an internal survey. In advance of the meeting, KCI made representative prototypes of three conceptual designs to facilitate discussions. The USAF staff offered their perspectives on current KCI products, ideas for the multichannel product, and feedback on the early concept prototypes.

The three concept prototypes were sent to the Air Force Medical Evaluation Support Activity (AFMESA) for evaluation of securing methods for flight. After summarizing notes and surveys from the meeting and AFMESA's feedback, the team translated that data into a list of user needs. This information then served as the platform for the system requirements.

In parallel to the documentation of the user needs and system requirements, the team also explored various device configurations by implementing USAF input into the first round of design concepts. The primary design tradeoffs were canister configuration, interface layout, securing methods, and overall size and weight of the device. Multiple new configuration options were explored, converging on a preferred design approach. Further design efforts worked through details of circuit board layout, internal component mounting, and manufacturability.

During the concept phase, the KCI design team began with the side-loaded canister prototype shown in Figure 1, a favorite of USAF staff during the kickoff and user needs meeting in July 2013. As the team more closely evaluated user needs, it became apparent that the proposed KCI 300-cc canister would not be sufficient to meet all user needs. After internal analysis and discussions with the USAF during monthly meetings, it was agreed that all four slots of the device would accept either the KCI 500-cc (or 1000-cc) canisters. Although the larger canisters would increase the size and weight of the device, it would better meet the larger

capacity needs of the expeditionary care staff and hospitals. Although the en route care staff were accepting of a 300-cc canister option, the larger canister could avoid the need to replace a full canister with an empty canister just prior to flight, taking advantage of the new approach of using the multichannel device through the continuum of care instead of changing to V.A.C.FREEDOM™ for air transport. All of these factors led to the added capacity and versatility of the larger canisters.

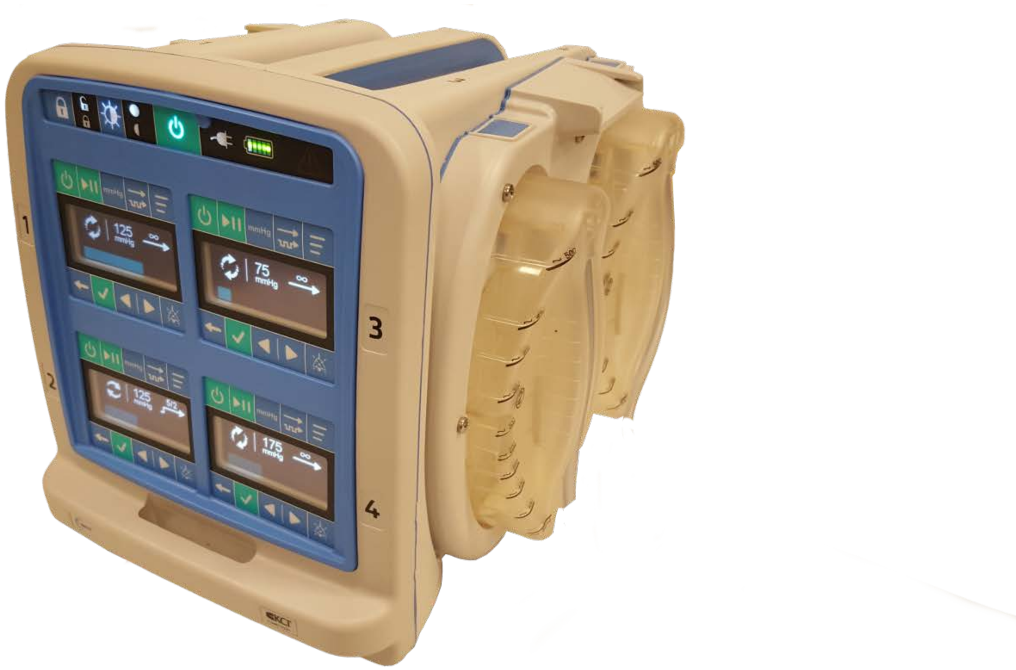

Figure 1. V.A.C.RX4™ (courtesy of KCI).

Since the canister size design decision did increase the envelope of the device, some styling features were adjusted to keep the design as compact as possible. With the configuration established, attention turned toward carrying and securing the device. Multiple design discussions internally and with the USAF led the design team to a recessed carry handle on the top and the ability to secure the device front to back or left to right. Features were added to make it intuitive as to where the strap needs to be placed to secure the device with strapping. With establishment of a basic feature set, a draft of the front panel user interface was created to facilitate discussion of controls and displays. The conceptual work included development of a tablet-based interactive simulation of the various features, controls, and notifications suggested by the prototype shown in Figure 2.

Figure 2. Side-loaded canister prototype (courtesy of KCI).

The phase ended by conducting a concept summary in November 2013 at KCI with USAF staff in attendance. The latest prototypes were presented and discussed. Feedback was provided as USAF staff examined the units and secured them with straps to a litter. The interface simulator was shown and features were discussed as well. In addition, a comparison between the original USAF internal survey and the current system requirements related to those items was discussed to drive alignment.

4.0 PLANNING PHASE

With the design configuration determined and reviewed at the concept summary, the design team began identifying purchased components, working with potential suppliers, and working through manufacturability details. Sealing of the plastic enclosure joints to meet the Joint Enroute Care Equipment Test Standard (JECETS) environmental tests was a major focus. The size and complexity of the enclosure concept presented a “jigsaw puzzle” of molded parts and sealing requirements that would not be easily manufacturable. Simplification of the design was needed.

The design team began researching other manufacturing methods and materials for the plastics. However, options like reaction injection molding did not produce an acceptable level of quality in terms of robustness or finish. Engineers decided to stick with injection-molded parts but changed the shape to allow construction of the enclosure using a “deep draw” main structure with gasketed components attaching to that structure. This reduced tooling costs, avoided complex gasket geometries for sealing, and simplified assembly.

In addition to the plastics design in progress, the embedded engineers spent time evaluating hardware components such as membrane buttons, liquid crystal display (LCD) display options, battery packs, and power supplies. A color LCD was chosen that was slightly larger than what was needed but commercially available, avoiding the need for a custom display. Battery pack and power supply requirements were provided to suppliers to obtain samples for initial testing.

With respect to the JECETS requirements, two existing KCI products (INFOV.A.C.™ and V.A.C.ULTA™) were sent to AFMESA for vibration profile testing. This was performed to

determine if the canister latching mechanism on these devices would meet JECETS criteria and subsequently could be used on the multichannel device. Results of that vibration testing indicated no issues for device functionality (mechanical and electronics) under the various profiles. The design team took the established configuration and continued to refine the design. The individual plastic pieces constituting the case of the device evolved, and another stereolithography (SLA) enclosure was built. This new prototype (Figure 3) was the first in which the individual planned components (Figure 4) were made separately and bolted together to create the final product.

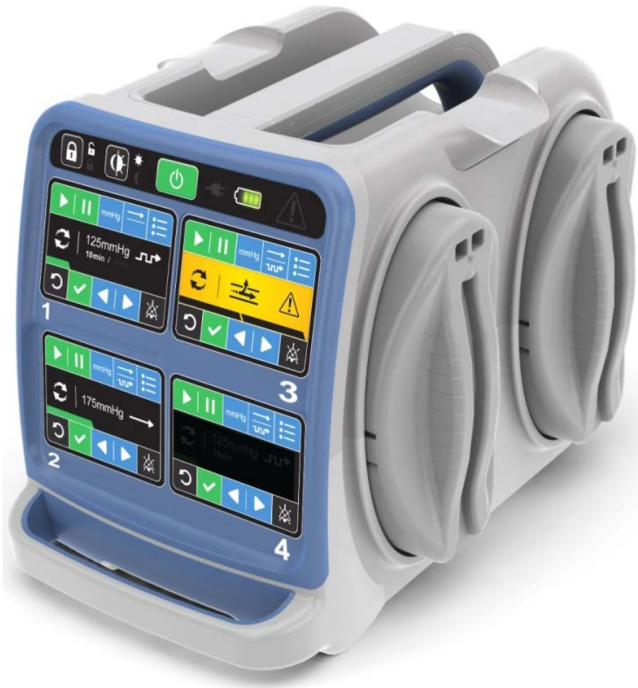

Figure 3. Concept summary prototype (courtesy of KCI).

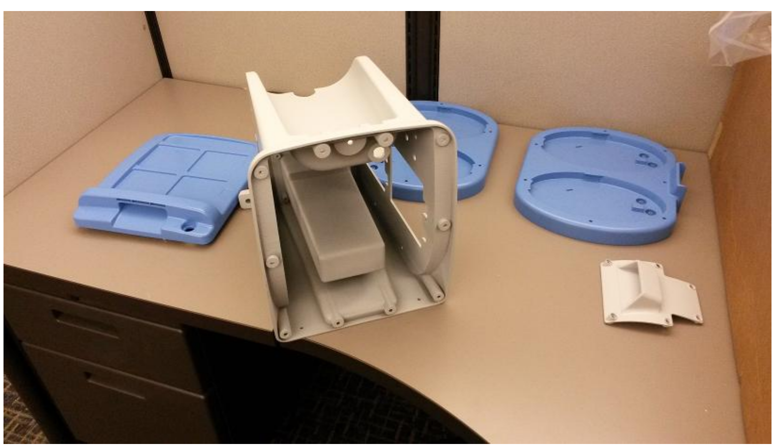

Figure 4. Individual parts (courtesy of KCI).

This prototype, in conjunction with a mock-up user interface panel (Figure 5), was used for the formative usability study to guide further design refinement. Three different power cord attachment points were included to gain user preference feedback. Overall, users appeared pleased with the device. Some clarifications were requested on the buttons and in the instructions for use.

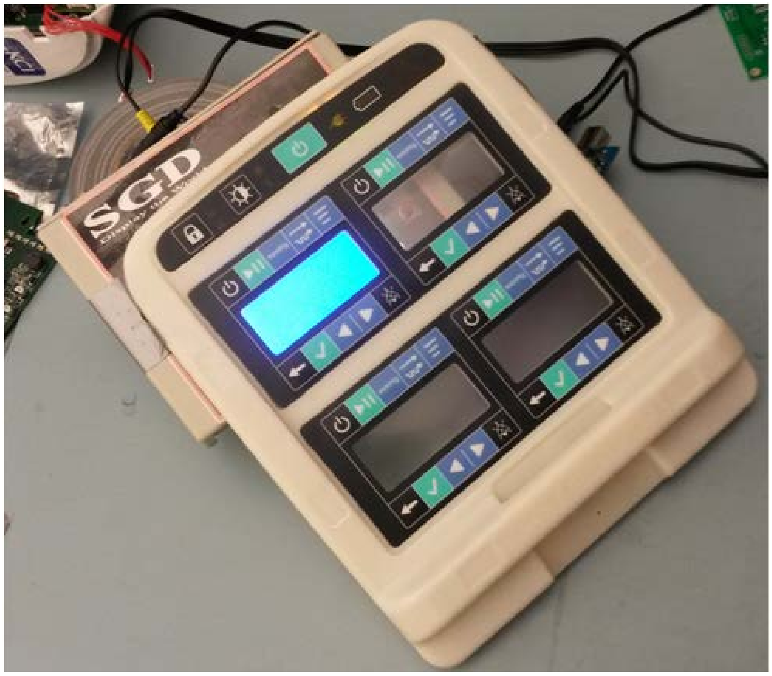

Figure 5. Front panel mock-up (courtesy of KCI).

As the design moved forward, decisions had to be made on the individual components of the device. Samples of the selected power supply and LCD display had been received, and battery pack samples had been ordered. Membrane panel options had been analyzed, and a supplier was chosen. Due to space and sealing constraints and the desire to maximize LCD display visibility, the front panel configuration had to be modified to use membrane panels for a pair of channels, instead of each individual channel. The device would include three different types of printed wiring assemblies (PWAs) located at various locations inside the case.

Next, KCI refined the design into a final configuration and prepared the final representative SLA models. The prototypes were made of individual plastic pieces and bolted together in the same manner as planned for actual devices. Two of these SLA devices were procured in advance of the planning summary review. Actual prototype membrane interface panels were part of these prototypes.

Samples of the selected power supply, LCD display, interface, and PWA boards had been received. These were installed into an old SLA front face and used to test the panel interactions with the LCD screen.

The KCI project manager traveled to the Food and Drug Administration (FDA) offices in August 2014 along with KCI Regulatory, Quality, and Medical staff. The purpose of the meeting was to familiarize some of the newer members of the FDA staff with KCI’s products and history. During the meeting, the multichannel project was also introduced to the FDA staff.

In September 2014, KCI conducted a planning summary at KCI with the USAF staff in attendance. The final non-working prototype and front panel mock-up were presented and discussed. Additional feedback was received from the USAF staff for implementation during the next phase.

5.0 DEVELOPMENT AND EVALUATION PHASE

This was the largest phase of the multichannel project, which was renamed to its commercial name of V.A.C.RX4. One of the PWA prototype boards experienced some power circuit challenges. The engineering group contacted the supplier of the power regulation integrated circuit, explained the observations of intermittent faults, and received guidance for design updates that were not available on the supplier website. With PWA boards arriving, software was being written and tested on the PWA as hardware availability allowed. Membrane panel prototypes had also been received. The individual channel interfaces worked well, and only minor graphical modifications were noted. Those modifications were implemented on the next units for the first engineering build.

Plastic SLA pieces were bolted together in the same manner as planned for actual devices along with actual pneumatic components for refinement of tubing and cable routing and assembly details for the device.

As scheduled, some of the small plastic parts had already been produced with the injection molding tools. These were very early parts and had not been dimensionally validated but were the first step toward receiving acceptable plastics for the 510(k) build.

During this period, KCI Design Assurance continued work on the risk documents. Method validations and verification and validation (V&V) protocols continued to progress. KCI Global Operations (GO) focused on coordination with KCI Manufacturing for preparations to complete an engineering build in January 2015. Athlone was also coordinating with the plastics vendor to evaluate the first plastic parts and begin preparing for secondary operations.

There was an initial teleconference among KCI, USAF, and the FDA military advisors to discuss next steps and how to make the 510(k) clearance go as smoothly as possible.

GO led the first engineering build of the V.A.C.RX4 to get an early start to develop manufacturing process documentation (Figure 6). As opposed to conducting this task at Athlone, the team brought two staff members from KCI Manufacturing to the San Antonio engineering facility for this build. This allowed proximity to the design team in case any questions were encountered. Other design team members were present during the build to help document the process and potential changes for manufacturing operations. Technical repair and service staff were also utilized to help perform the actual build and offer input on potential serviceability items.

As expected, the first engineering build generated a list of design items to address since it was the first time that the pieces were being assembled. The design team immediately began looking for solutions for the noted items from the build, accommodating manufacturing preferences and opportunities to improve the design.

Figure 6. V.A.C.RX4 unit #1 (courtesy of KCI).

Software development continued, and several versions of software were released to V&V to begin dry run tests, evaluating both the software functionality as well as accuracy of software test protocols. Some early electromagnetic compatibility (EMC) testing revealed a couple of frequency ranges of concern, leading to testing of alternative solutions for effectiveness. KCI Regulatory Affairs (RA) submitted a presubmission meeting request to the FDA. As a result of the expedited review request letter from the USAF, RA was provided with a meeting somewhat sooner than the FDA guidelines. The focus of the request was usability testing, since that had been a topic of recent discussions with the FDA. Several usability draft documents were provided with the presubmission meeting request as discussion items for the upcoming meeting with the FDA.

A conference call was conducted on the subject of testing among team members from both the USAF and KCI. In that meeting, KCI's draft test matrix, which listed proposed tests in each of several categories, was discussed. With several units available from the engineering build, bench testing began to evaluate the higher risk items.

With the first engineering build completed, the design team focused on incorporating design modifications and updating documentation. The mechanical design was mostly completed, and production drawings were released. Other efforts were focused on embedded concerns, including EMC testing and software stability. While new versions of software could be tested quickly, PWA design iterations each required a couple months of time between rounds of testing.

GO began preparing for the upcoming design verification build producing units in sufficient quantity in a documented, controlled build for use in V&V testing. This included not only ordering components for the build but creating processes and work instructions for building the units. Validation of components through first article inspections and review of supplier process documentation was also done during that period to ensure quality procedures would be met.

RA led a presubmission meeting with an extensive group of FDA, KCI, and USAF team members. Feedback was provided and discussed with regard to the summative usability protocol. Changes were implemented into the protocol, which was submitted back to the FDA as a supplement per FDA direction. Feedback on the updated protocol was requested of the FDA prior to conducting the summative usability study.

In June 2015, KCI conducted a Program Management Review and Development Update at KCI with USAF staff in attendance. The discussion included review of V.A.C.RX4 features, manuals, service and repair aspects, testing plans, regulatory status, and production preparations. Changes had been made to the PWA to address EMC issues. The new boards arrived and were tested at a local EMC test facility. The embedded team began working closely again with the supplier of the power regulation integrated circuit to update the power circuit, which was identified as the main source of the noise. Multiple design modifications were implemented and analyzed by testing small changes to the power circuit only. A combination of multiple circuit changes resulted in acceptable EMC test results, which avoided a riskier change of the actual power chip to another supplier.

Software development continued and eventually uncovered an undocumented processor design issue that caused compatibility problems with double data rate style memory. As opposed to waiting for the processor supplier to modify its silicon and prove the design fix, the embedded systems team modified the board design to instead use static random access memory to avoid the double data rate processor interface issue. This also required a change of the flash memory from NAND style to NOR style. This was an extensive change to both hardware and software, but it was the fastest path with the least risk.

The updated design was sent to the board manufacturer in August 2015. The team decided to delay the summative usability test until the new boards were received and updated software was tested to reduce the chance of possible contamination of summative testing results. Work also continued with the plastics manufacturer as part of the normal process of improving the molding process to improve part quality from first run parts.

The KCI Global Product Labeling group updated the user manual (UM) and quick reference guide (QRG) for use in the next formative usability study. Feedback from that study would then be implemented for the summative usability study.

RA continued to provide guidance while waiting for the documents necessary for the 510(k) filing. These included the 60601 report, the summative test report, device labeling, software V&V, and substantial equivalence testing (comparative test of subject device V.A.C.RX4 to the predicate). These tasks required units built with production equivalent hardware and software.

Finally, testing confirmed that the design features to lower the EMC issues were successful. Software development completed a major milestone with implementation of all planned features and completion of software V&V testing to allow start of summative usability testing and the FDA submission.

GO completed the design verification build and related reports. KCI Global Product Labeling produced the reviewed and approved version of the UM, QRG, and safety information sheet for use in the summative usability testing. Early drafts of the service manual (SM) and repair manual (RM) were in process as well. The usability group completed the summative usability testing and related reports for submission to the FDA.

RA submitted the 510(k) filing in February 2016. The FDA responded with questions, which were discussed in a group call and answered by KCI within the time provided. The FDA accepted the KCI submission on 17 March 2016 and officially approved the project for expedited review at the request of the USAF.

In April 2016, USAF members traveled to KCI for a review of the UM, QRG, safety information sheet, and drafts of the SM and RM documents. The meeting included chances for attendees to use the manuals to operate, tear down, and reassemble actual units. Feedback was provided to improve the final SM and RM.

With usability complete, the two major testing efforts were V&V testing and pre-JECETS testing. V&V was required as part of KCI procedures for medical device development. The pre-JECETS testing was a joint effort with KCI resources and USAF resources to conduct an agreed list of JECETS tests on V.A.C.RX4 units to gather those results prior to official JECETS evaluation by the USAF. A report on the pre-JECETS testing is being sent to the USAF under a separate transmittal. This information will be an indicative report as reference for the USAF when they perform official JECETS testing on the contract-deliverable production representative units (Not for Human Use).

6.0 CONCLUSIONS

The scope of this Technology Investment Agreement was completed at the end of June 2016, including delivery of the final report, pre-JECTS report, and shipment of the five units. This resulted in a total time of 3 years and 1 month from contract award date (Figure 7).

The cost and schedule of the contract increased over its life due to a couple main scope modifications. The first is that the original scope was for a four-channel device with 300-cc canisters, very simple interfaces, and no display screens. At the request of the customers, the design grew to a larger and more complicated assembly that offered 500-cc (or 1000-cc) canisters and full color display screens.

The other challenge was related to the electronics of the device. EMC testing began in February 2015 and took until near the end of that year for design modifications to allow passing of the necessary testing due to unexpected interactions and efforts to ensure adequate margins.

Despite the challenges, the project went from a clean sheet of paper to a product that was tested for medical devices and JECETS criteria as well as submitted to the FDA for 510(k) clearance in approximately 3 years. The feature set was chosen based on direct teaming with customers and what was really needed for the intended use. This lean approach resulted in an interface that was very easy to use as demonstrated by usability testing, despite the fact that four channels had to be controlled simultaneously.

	% Complete	Task Name	Duration	Start	Finish
✓	100%	− 7252 VACRx4 Therapy System	243.6w	11/1/11	6/30/16
✓	100%	− 1 Project Administration	243.6w	11/1/11	6/30/16
✓	100%	+ 1.1 Contract Award	82.2w	11/1/11	5/28/13
✓	100%	+ 1.2 Deliverables	161.4w	5/29/13	6/30/16
✓	100%	− 2 Concept	18w	5/29/13	10/1/13
✓	100%	+ 2.1 Concept Project Management	18w	5/29/13	10/1/13
✓	100%	+ 2.2 User Needs	12.7w	5/29/13	8/26/13
✓	100%	+ 2.3 Preliminary System Requirements	17.2w	5/29/13	9/25/13
✓	100%	− 3 Planning	64.4w	6/13/13	9/5/14
✓	100%	+ 3.1 Planning Project Management	40.3w	10/7/13	7/15/14
✓	100%	3.2 Schedule	6.46w	10/2/13	11/15/13
✓	100%	+ 3.3 Risk Management	9w	10/7/13	12/9/13
✓	100%	3.4 System Requirements	6.54w	10/7/13	11/21/13
✓	100%	3.5 Identify and design concepts	10.72w	10/7/13	12/20/13
✓	100%	+ 3.6 Build concept prototypes	43.6w	6/13/13	4/14/14
✓	100%	+ 3.7 Sub-system Requirements	41.9w	11/18/13	9/5/14
✓	100%	− 4 Development/Evaluation	241.2w	11/1/11	6/14/16
✓	100%	+ 4.1 D/E Project Management	100w	7/15/14	6/14/16
✓	100%	+ 4.2 FMECA	98.6w	7/16/14	6/3/16
✓	100%	+ 4.3 Design Specifications	232.6w	11/1/11	4/14/16
✓	100%	+ 4.4 Release Drawings	43.4w	9/8/14	7/7/15
✓	100%	+ 4.5 Labeling	114.2w	3/6/14	5/12/16
✓	100%	+ 4.6 Systems Testing	85.2w	9/8/14	4/25/16
✓	100%	4.7 V&V Protocols	33w	2/24/14	10/13/14
✓	100%	+ 4.8 Design Verification Build	111.8w	2/25/14	4/18/16
✓	100%	+ 4.9 V&V	89w	9/5/14	5/20/16
✓	100%	+ 4.10 FDA Submission	84.7w	7/7/14	2/18/16

Figure 7. Final schedule.

The result was a device that improved the footprint and efficiency of the current standard of flight care, four V.A.C.FREEDOM devices. This new alternate, the V.A.C.RX4 device with four channels, simplified handling of multiple trauma wounds with a single control interface, allowed more convenient portability, and had provision for securing while in flight. It also provided increased pump power and battery life compared to the V.A.C.FREEDOM, making it more equivalent in mechanical and electrical performance to four INFOV.A.C. devices (see Figure 8 for comparisons). This collaborative project effort resulted in a better solution for the USAF that would not have been available in a commercial off-the-shelf product and will be available in the civilian market as well.

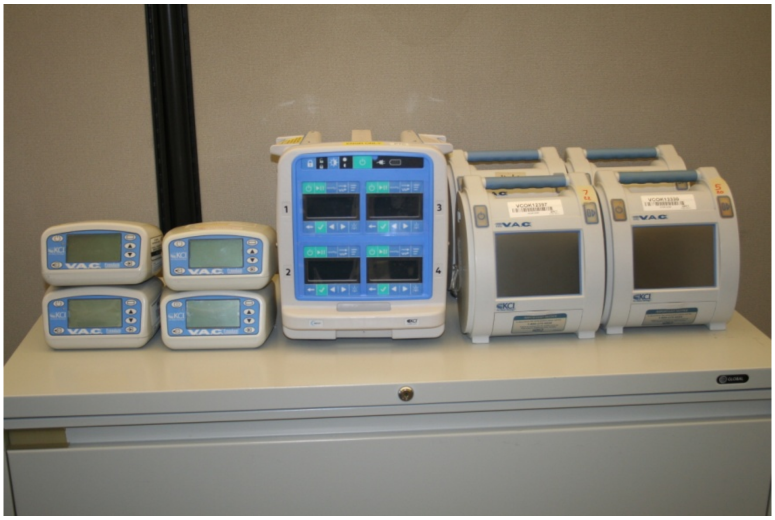

Figure 8. Left to right: V.A.C.FREEDOM units (4), V.A.C.RX4 unit, INFOV.A.C. units (4) (courtesy of KCI).

LIST OF ABBREVIATIONS AND ACRONYMS

AFMESA	Air Force Medical Evaluation Support Activity
EMC	electromagnetic compatibility
FDA	Food and Drug Administration
GO	Global Operations
JECETS	Joint Enroute Care Equipment Test Standard
KCI	Kinetic Concepts, Inc., division of Acelity
LCD	liquid crystal display
QRG	quick reference guide
PWA	printed wiring assembly (circuit board)
RA	Regulatory Affairs
RM	repair manual
SLA	stereolithography
SM	service manual
USAF	United States Air Force
UM	user manual
V&V	verification and validation
V.A.C.	vacuum assisted closure
V.A.C.RX4™	multichannel product commercial branding name